K070617

JUN 14 2007

# 510 (K) SUMMARY
# CANNULATED SCREWS

*This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92*

**SUBMITTER :**
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**COMPANY CONTACT :**
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General Manager
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**Date prepared :** January 31th 2007

**DEVICE NAME :**
**Trade name :** CANNULATED SCREWS
**Common name :** Cannulated screw
**Classification name :** Smooth or threaded metallic bone fixation fastener
21 CFR 888.3040

**PREDICATE DEVICES :**

**Manufacturer :** **Fournitures Hospitalieres Industrie**
Device Trade Name : Snap-off screws
510 (K) : K041456
Date claered : August 25th 2004

**Manufacturer :** **NewDeal SA**
Device Trade Name : BOLD® screw
510 (K) : K990622 and K011262
Date claered : June 15th 2001 and April 29th 1999

**Manufacturer :** **MEDINOV-AMP**
Device Trade Name : Scarf Thread-Head screw
510 (K) : K971070 and K962236
Date claered : July 9th 1997 and September 20th 1996

**DEVICE DESCRIPTION:**
This range of screws for foot includes several types of cannulated screws made of titanium alloy (according to ISO 5832/3 and ASTM F 136) with an hexagonal head.

- The cannulated self-compression screw, and
- The cannulated arthrodesis screw.

A specifical guide pin is used for implant placement.
The following table shows our range of cannulated screws:

| Products | Lengths |
|---|---|
| Cannulated self-compression screw | 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34mm |
| Cannulated arthrodesis screw | 28, 30, 32, 34, 36, 38, 40mm |

**INDICATIONS FOR USE:**
The screws are used to fix bone fragments of the foot together for osteosynthesis.

**PREDICATE DEVICES:**
Numerous cannulated screws for foot have been cleared for commercial distribution by the Food and Drug Administration (FDA). We have selected two predicate devices based upon intended uses, material used in device manufacturing and design features.

These predicate devices are:

- Snap-off screws (K041456) manufctured by FH Industrie
- BOLD Cannulated Compression screw (K990622 and K011262), manufactured by Newdeal,
- Scarf Thread-Head screw (K971070 and K962236) manufactured by Medinov-AMP.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:**
The cannulated screws have the same intended use and substantial similar indications for use as the predicate devices. They are all made of the same material (titanium alloy), are available in similar diameters and lengths, with similar designs.

**PERFORMANCES:**
Rupture torque was performed on our cannulated screws and was compared with the requirements of the French Standard NF F 90-414 and found to have a resistance to torsion in compliance with the selected standard.

Risk to health have been addressed through the specified materials, Processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.

**CONCLUSION:**
All these elements show the safety and effectiveness of our product. The cannulated screws are substantially equivalents to the selected predicate devices in terms of intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fournitures Hospitalieres Industrie
c/o Ms. Patricia Donnard
Regulatory Affairs Manager
6 Rue Nobel
Z.I. de Kernevez
29000 Quimper, France

JUN 14 2007

Re: K070617
Trade/Device Name: Cannulated Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 7, 2007
Received: May 16, 2007

Dear Ms. Donnard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or on the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): _K070617_____

Device Name: CANNULATED SCREWS
The complete range of screws indicated for the foot includes the two following models :
- the cannulated arthrodesis screw ; and
- the cannulated self-compression screw.

Indications for Use: The screws are used to fix bone fragments of the foot together for osteosynthesis.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over the counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Barbara Brenner

**(Division Sign-Off)** Concurrence of CDRH, Office of Device Evaluation (ODE)

**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K070617